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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WALLENHORST, MAUREEN

ART UNIT PAPER NUMBER

1743

DATE MAILED: 01/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/284,421

Applicant(s)

GORDON, JOHN FRANCIS

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 89-99, 105, 107, 108, 110-123, 125-131 and 156-158 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 89-99, 105, 107, 108, 110-123, 125-131 and 156-158 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

2. Claims 119-120 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 2 of claim 119, the phrase "the disc" lacks antecedent basis. This phrase should be changed to --the structure--.

On lines 1-2 of claim 120, the phrase "the disc" lacks antecedent basis. It is suggested to rewrite claim 120 as: The structure of claim 119 wherein the structure and the insert include lock and key portions to allow the insert to be snap-fitted to the structure in a correct orientation only.--

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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5. Claims 89-94, 96-99, 105, 107-108, 110-113, 116, 121-123, 125-127, 129-131 and 156-158 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (WO 96/09548) in view of Kelton et al (US Patent no. 5,496,520, newly cited).

Gordon teaches of an apparatus for conducting the optical inspection of a biological, chemical or biochemical sample supported on an optically transparent disc. The apparatus comprises a substrate having a surface for supporting a sample, a source of electromagnetic radiation for providing a beam of electromagnetic radiation, a means for scanning the beam across the surface of the substrate, and a detector means arranged to detect electromagnetic radiation reflected and/or transmitted through the substrate, wherein the substrate is provided with digitally encoded information thereon that is scanned by the beam of electromagnetic radiation and that contains information indicative of the address or location on the surface of the substrate which the beam is currently directed. The detector means is arranged to decode the electromagnetic radiation beam to determine the encoded address and to determine if the received beam has been modulated by any of the sample on the substrate. The provision of address information in or on the substrate enables the precise position of the electromagnetic radiation beam on the surface to be determined which in turn allows the accurate mapping of optical data, corresponding to attached material, on the surface. The substrate is provided in the form of a circular disc 1 that has a surface for supporting a sample and a surface with a plurality of perturbations that represent the digitally encoded data. The disc 1 comprises upper and lower layers of transparent plastic 2, 3, with a reflective layer sandwiched in-between. A lens arrangement 10 is located on the disc structure. In the embodiment depicted in Figure 6 of Gordon, the disc 44 comprises a plurality of wells or indentations 51 formed in its upper surface.

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The wells contain different samples to be inspected. Gordon also teaches that it is possible to construct the disc in such a way that the support surface is internal to the disc and is not the upper surface of the disc. This provides the advantages that the sample is not damaged by handling and that a precise volume of sample is analyzed. See pages 3-4, 7, 10, 12, 14 and 22-23 of Gordon. Gordon qualifies as a reference under 35 USC 102(b) since it was published on March 28, 1996, which is more than one year from the effective filing date of the instant application (i.e. August 10, 1997). Gordon fails to teach that the disc has an upper surface and a lower opposed surface with a space there between with reaction sites on the lower surface and an opening in the disc for allowing a sample liquid to be introduced into the space by capillary action between the upper and lower surfaces.

Kelton et al teach of a rotary fluid manipulator that is used to perform different types of diagnostic assays such as immunoassays. The device comprises a two part housing 12 consisting of an upper, substantially planar, rigid surface 14 and a lower, substantially planar, rigid surface 16. Located between the upper and lower surfaces is a body 20 that is impregnated with different reagents such as antigens and antibodies for reacting with a sample fluid. The body 20 is divided into a plurality of sections 26 so that a separate assay may be accomplished in each of the sections. Radial slots 28 define each of the sections 26 and prevent fluid from migrating into adjacent sections 26. The upper and lower surfaces 14 and 16 are connected to one another with a space there between holding the body 20. An enlarged central opening or aperture 50 is located in the planar, rigid surface of upper surface 14 that serves as an eluant dosing aperture to permit eluant to be fed into an eluant receiving area 24 on the body 20. In addition, the upper surface contains a plurality of specimen dosing orifices 52 which permit specimens to be applied

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to the different sections 26 in the body 20. With the device taught by Kelton et al, the specific reagents (i.e. antibodies and antigens) to be reacted on a disc structure are kept isolated from the outside environment by the upper and lower surfaces 14, 16, and a central opening 50 in the upper surface is used for dispensing reagents to the reactants on the disc structure. See Figures 1-3, lines 59-67 in column 3, lines 33-63 in column 4, lines 26-39 and 59-67 in column 5 and lines 1-51 in column 6 of Kelton et al.

Based upon the combination of Gordon and Kelton et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide the disc taught by Gordon with upper and lower closely spaced surfaces with a space there between having an opening for introducing and removing sample liquids, similar to the configuration of the assay device taught by Kelton et al, in order to protect the reaction sites on the disc from contamination present in the environment, especially in light of the suggestion by Gordon that the disc may be constructed so that the reaction sites are internal to the disc to provide the advantages that the sample is not damaged by handling and that a precise volume of sample is analyzed.

6. Claims 95, 114-115, 117-120 and 128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon in view of Kelton et al as applied to claims 89-94, 96-99, 105, 107-108, 110-113, 116, 121-123, 125-127, 129-131 and 156-158 above, and further in view of Merkh et al. For a teaching of Gordon and Kelton et al, see previous paragraphs in this Office action. Gordon fails to teach that the disc assay plate is subdivided into removable sectors by dividing walls.

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Merkh et al teach of a disc structure 18, which is divided into sector inserts 80 comprising wells 84. The system of Merkh et al includes a liquid injecting device 31, which penetrates the self-sealing cover 90 of each sector at port 92 (see column 10, lines 1-7). The sector inserts 80 and the disc 18 include locks 100, 102, 104 and key 93 portions to allow the sectors to be snap-fitted in the correct orientation on the disc 18. Additionally, the disc comprises a plurality of dividing walls 131.

Based upon the combination of Gordon, Kelton et al, and Merkh et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to subdivide the disc assay plate taught by Gordon into removable sectors separated from one another by dividing walls, similar to the configuration of the disc plate taught by Merkh et al, so as to provide means for analyzing a plurality of samples applied to the different sectors at the same time while keeping the samples separated from one another to avoid contamination, thus allowing more tests to be run in a given amount of time.

7. Applicant's arguments filed October 17, 2005 have been fully considered but they are not persuasive.

The previous objection to the abstract and the previous rejections of the claims under 35 USC 112, second paragraph made in the last Office action mailed on June 3, 2005 have been withdrawn in view of the amendments made to the abstract and the claims. However, claims 119-120 are rejected under 35 USC 112, second paragraph, as set forth above, as necessitated by Applicant's amendments to the claims.

Applicant's arguments with respect to the previous rejections of the claims under 35 USC 103 as being obvious over Gordon in view of Croteau et al, and further in view of Merkh et al,

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are moot since the reference to Croteau et al has been withdrawn. Therefore, these arguments will not be addressed. The reference to Kelton et al has been applied as a new secondary reference in the rejection of the claims under 35 USC 103, as necessitated by Applicant's amendments to the claims concerning the upper and lower surfaces of the assay plate structure being substantially planar and rigid, and the at least first opening being located in either one of the upper or lower planar, rigid surfaces. Because the new grounds of rejection are necessitated by Applicant's amendments to the claims, this Office action is being made final.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

January 4, 2006

Maureen M. Wallenhorst

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